Human Research Program Flight Experiment Information Package

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Introduction

This Flight Experiment Information Package (FEIP) will provide some basic information for investigators proposing human life sciences studies for the International Space Station (ISS). Top level information is provided regarding restrictions on performing flight research, and reference information is provided on research hardware that is available.

1.0Guidelines for Human Life Sciences Flight Investigations

In general, resources such as upmass, downmass, cold storage and post-flight Baseline Data Collection are limited. Thus, experiments that require fewer of these resources will be more feasible to implement. Due to the planned retirement of the Space Shuttle in 2010, experiments should only be proposed that utilize the ISS and long duration crewmembers as subjects.

Flight experiment proposals must represent mature studies strongly anchored in previous or current ground-based or flight research. For a flight experiment proposal, ground-based research should be limited to activities that are essential for the final development of an experiment for flight, such as definition of flight procedures and control activities for the flight experiment. In this case, only one (flight) proposal needs to be submitted.

1.1 Research Involving Human Subjects

All use of human subjects for research must comply with NASA Policy Directive NPD 7100.8D, Protection of Human Research Subjects:
(http://nodis3.gsfc.nasa.gov/displayDir.cfm?Internal_ID=N_PD_7100_008E_&page_name=main).
Informed consent of human subjects must be obtained prior to carrying out any study in space, and potential applicants should be aware that obtaining such informed consent will involve a uniform process. The availability of consenting subjects may impact the probability of achieving experiment objectives within the expected timeframe.

1.2 Flight Hardware Available

There are many research tools available to investigators who wish to conduct human physiological research on ISS. The ISS Human Research Facility (HRF) is a suite of hardware that provides core capabilities to enable research on human subjects. HRF consists of items mounted on two racks located in the US Lab, as well as separate equipment kept in stowage and brought out as needed. HRF Racks 1 and 2 are currently on orbit. More information on the HRF hardware is available at: https://issmp.jsc.nasa.gov/hardware.asp . The European Space Agency (ESA) will also be launching several hardware facilities designed for use in human life sciences experiments. Information about these facilities can be found at: http://spaceflight.esa.int/users/virtualinstitutes/epm/index1.html. Investigators should be aware that while these ESA facilities will be onboard ISS, use of them by NASA investigators will have to be negotiated. Hardware is available on board ISS for investigations that require conditioned storage of samples. Information about these facilities can be found at:
http://iss-www.jsc.nasa.gov/nwo/payload/oz2/web/ColdStow.shtml

Some investigators may wish to develop their own special experiment hardware to work in conjunction with the facilities and functional capabilities of existing hardware. Development of experiment-unique equipment will require additional funding, which may negatively impact the overall assessment of the experiment feasibility. Design, construction, and flight of major experiment-unique equipment hardware items or facilities usually require the commitment of large quantities of resources (power, crew time, volume). In the event that such items are proposed, they should be clearly identified. Proposals for major hardware items or facilities to be developed by the investigator will not be considered.

Flight experiment proposals must clearly define the actual experiment duration and all requirements and conditions required to successfully complete the experiment. The investigator should allow for flexibility in the selection of the best hardware to be used to accomplish the experimental goals.

1.3 Difficult Experimental Requirements to Implement

There are certain human life sciences experimental requirements that, while not impossible to perform, are difficult to implement. Investigators should consider these limitations when developing their experiment protocols, knowing that technical feasibility is an important part of the overall assessment. The Flight Experiment Resources Worksheet specifically addresses several of these requirements, and investigators should fill this out carefully in order for technical reviewers to better understand your requirements. Those requirements that may be difficult to accommodate include:

1. Baseline Crew Data Collection on landing day and the first week post-flight (R+0 through R+7). All crew landings will take place via the Soyuz until the Orion vehicle is operational, and access to the crew on landing day is extremely limited. Immediate access to the crew after landing for testing is not possible. Any extensive testing required immediately after landing must be able to be accommodated on R+1 and must be able to be performed in Russia. Access to the crew for multiple and lengthy sessions in the first week post-flight will not be feasible to implement.
2. Baseline Crew Data Collection during the 30 days prior to launch (L-30 to Launch). This is a very busy time for the crew and scheduling any significant activities is difficult. In addition, the crew travels to the launch site around L-15 days, where there are no BDC facilities available for investigator use.
3. Early in-flight activities: All long duration crewmembers will be launching via the Soyuz, therefore operations during the first day in orbit will not be possible until they dock with the ISS. In addition, operations within the first 2-3 weeks on orbit can be difficult to schedule as this is typically a very busy time. Operations during this time should be limited to only what is truly required and allow for flexibility in scheduling.
4. Excessive Crew Training (more than 10 hours to familiarize a novice with the procedure).
5. A large number of crew subjects (more than 6).
6. Complex or invasive inflight procedures on the crew, such as indwelling catheters, multiple hardware items that must be integrated or synchronized, precise requirements for when an experiment must be performed, complex skills requiring extensive training pre-flight.
7. Large Upmass/Volume: Volume requirements for hardware that must be launched to ISS is commonly measured in "Middeck Locker Equivalents (MLE)." This is equivalent to a shuttle middeck locker volume with dimensions of (44.0 x 25.3 x 51.6 cm) (17.337 x 9.969 x 20.320 in.) and can hold a total of 27.2 kg (60 lbs). Due to limited upmass capabilities, experiments requiring more than 1-2 MLEs will be difficult to accommodate.
8. Large Downmass/Volume: After 2010, there will very limited capabilities for returning hardware, samples, or electronic media from ISS. Experiments that require frequent or large amounts of return capability will be difficult to implement.
9. Unique or excessive cold stowage requirements. Experiments requiring cold stowage temperature requirements that cannot be met with the equipment provided by the ISS cold stowage team will likely not be considered. In addition, experiments that require a significant amount of cold stowage to be maintained on board ISS or returned will be difficult to implement.

1.4 Flight Experiment Implementation

It is very important for investigators to carefully and completely fill out the Flight Experiment Resource Worksheet as part of their Phase 2 proposal, as this information is the primary tool used by the technical reviewers to determine the feasibility of implementing the experiment on ISS. Investigators should be aware that if they are selected for definition, they will be assigned an experiment team experienced in conducting human life sciences investigations on ISS to assist them in further defining their experiment and hardware requirements.